COGENT

Section E
510(k) Summary

1. Prepared On: 31 May 2000

   Submitted By: Cogent Light Technologies
   26145 Technology Drive
   Santa Clarita, CA 91355-1137
   800-294-2989

   Contact: Ed Currie
   Director of Quality

2. Device Name: Micro Link® Endoscopic Fiber Cable
   Common Name: Endoscopic Fiberoptic Cable
   Classification Name: Illuminator, Fiberoptic, for Endoscopes (per 21 CFR section 876.1500)

3. Comparison Devices

   a) CUDA Products, Universal Fiberoptic Cable (510(k) K901035), Model YELS3.0W225
   b) Isolux America, Endoscopic Fiberoptic Cable (510(k) K991208)

4. Description of the Device

   The Micro Link® Endoscopic Fiber Cable is a ten-foot, multi-use lightweight light cable designed for use with the SolarTec™ family of illuminators. The fiber cable is sold non-sterile but designed for user sterilization by Ethylene Oxide, Steris, Sterrad and Liquid Chemical sterilization methods and is rated for 20 uses maximum. The fiber cable is designed to deliver the light energy output of SolarTec™ family illuminators to endoscopes and other surgical instruments equipped with standard endoscopic adapters.

   The Micro Link® Endoscopic Fiber Cable uses an optical grade acrylic fiber to transmit light, which is clad in a Teflon tube covered by a silicone outer sheath. Connectors are attached to the fiber ends to allow connection with a Cogent Light SolarTec™ series illuminator on one end, and endoscopes, endoscopic tools, and other lighted instruments on the distal end. The entire assembly is sealed to protect the acrylic fiber quality through use, handling, and sterilization.

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5. Intended Use and Indication for Use

The Micro Link® Endoscopic Fiber Cable is a ten-foot, multi-use lightweight light cable designed for use with the SolarTec™ family of illuminators. The fiber cable is sold non-sterile but designed for user sterilization by Ethylene Oxide, Steris, Sterrad and Liquid Chemical sterilization methods and is rated for 20 uses maximum. The fiber cable is designed to deliver the light energy output of SolarTec™ family illuminators to endoscopes and other surgical instruments equipped with standard endoscopic adapters.

6. Substantial Equivalence Comparison – Safety and Efficacy

The Micro Link® Endoscopic Fiber Cable is substantially equivalent to the CUDA Universal Fiberoptic Cable and the Isolux America Endoscopic Fiberoptic Cable as follows:

a) All three connect illuminators to endoscopic instruments (same intended use)
b) All three are indicated for endoscopic procedures requiring illumination
c) All three transmit visible light from the illuminator to the instrument
d) None of the three are intended to contact the patient
e) All three are sold nonsterile
f) All three are cleanable and sterilizable by the user
g) All three are silicone jacketed with metal or plastic end connectors

The Micro Link® Endoscopic Fiber Cable is different from the CUDA Universal Fiberoptic Cable and the Isolux America Endoscopic Fiberoptic Cable in using single fiber technology rather than a fiber bundle. Fiber bundle uniformity depends on the number of remaining intact fibers (individual fiber strands will break over the use of the device) and the space between fiber strands (which causes shadowing). Single fiber light output is more uniform than fiber bundles because it is a solid fiber (no degradation due to fiber strand breakage or shadowing).

The second difference is the use of optical grade acrylic for the single fiber instead of quartz for the bundles. The acrylic is lighter weight, lower cost, and more durable than quartz fibers. Due to Cogent Light's proprietary illuminator technology, the amount of light delivered through the acrylic single fiber is equivalent to larger quartz fiber bundles. However, because the acrylic cannot withstand the temperatures associated with typical autoclave sterilization cycles the device will be labeled "Do not autoclave." Other common sterilization methods have been validated.

The final difference is the Micro Link® Endoscopic Fiber Cable is made with specific end connectors: the Illuminator side connector fits only SolarTec™ series illuminators and the endoscopic tool side connector fits with many, but not all, endoscopic tools. The devices used for equivalency can be ordered with many types of end connectors to connect to almost all available illuminators and endoscopic tools.

None of the differences affect the conclusion of equivalence for safety and efficacy between the Micro Link® Endoscopic Fiber Cable and the devices used for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2000

Mr. Ed Currie
Director of Quality
Cogent Light Technologies, Inc.
26145 Technology Drive
Santa Clarita, California 91355-1137

Re: K001698
Micro Link Endoscopic Fiber Cable
Dated: May 31, 2000
Received: June 2, 2000
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FFS & KOD
21 CFR 878.4580/Procode: 79 HBI & FST

Dear Mr. Currie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Section D
Statement of Indications for Use

The Micro Link® Endoscopic Fiber Cable is a ten-foot, multi-use lightweight light cable designed for use with the SolarTec™ family of illuminators. The fiber cable is sold non-sterile but designed for user sterilization by Ethylene Oxide, Steris, Sterrad and Liquid Chemical sterilization methods and is rated for 20 uses maximum. The fiber cable is designed to deliver the light energy output of SolarTec™ family illuminators to endoscopes and other surgical instruments equipped with standard endoscopic adapters.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001698

Prescription Use ✓
(Per 21 CFR 801.109)